Medacta International

510(k) Summary

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AUG 2 2 2013

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Date Prepared: April 25, 2013

DEVICE INFORMATION

Trade/Proprietary Name: GMK Full PE Tibial Components
Common Name: Total Knee Prosthesis
Classification Name: Knee joint patellofemorotibial polymer/metal/polymer semi-constrained cemented prosthesis
21 CFR 888.3560
Class II
Device Product Codes: JWH

Predicate Devices:

510(k)	Product	510(k) Holder	Clearance Date
K951987	Genesis II CR	Smith and Nephew, Inc.	08/22/1995
K953274	Genesis II PS	Smith and Nephew, Inc.	02/05/1996
K090988, K113571, K120790, K122232	GMK Total Knee System	Medacta International	7/10/2009,1/27/2012, 6/8/2012, 9/28/2012
K081023	Evolis Total Knee System	Medacta International	10/22/2008
K991581, K042271	NexGen LPS	Zimmer	7/30/1999, 10/13/2004
K070214	Natural Knee	Zimmer	3/16/2007

Product Description

The GMK Full PE Tibial Components are symmetric and come in ultracongruent and posterior-stabilized designs in sizes 1-6 with thicknesses of 10, 12, 14, and 17mm and have an axial rotation of +/- 10°. The GMK Full PE Tibial Components are made from UHMWPE (ISO 5834 -2) Type 1. There are two radiopaque wires made of AISI 316 LVM (ISO 5832-1) to check the final implant position during radiography.
The GMK Full PE Tibial Components can be used in place of the metal backed solution (K090988), where a component entirely made of UHMWPE replaces the metal backed solution (metallic tibial tray + UHMWPE tibial insert, K090988).

Indications for Use

The GMK® Total Knee System is designed for cemented use in total knee arthroplasty, if there is evidence of sufficient sound bone to seat and support the components.

This knee replacement system is indicated in the following cases:

- Severely painful and/or disabled joint as a result of arthritis, traumatic arthritis, rheumatoid arthritis or polyarthritis.
- Avascular necrosis of femoral condyle.
- Post traumatic loss of joint configuration.
- Primary implantation failure.

Tibial augments are to be attached to the tibial baseplate with both the fixing cylinders and bone cement.

If a semi-constrained insert is used, it is mandatory to implant an extension stem both on the tibial and the femoral components.

Comparison to Predicate Devices

The indications for use, design features, and materials of the subject device are substantially equivalent to those of the predicate devices. The design features of both the GMK Full PE Tibial Components and the predicates come in ultracongruent and posterior-stabilized designs in similar sizes and thicknesses. The GMK Full PE Tibial Components and the predicates are both made of UHMWPE (ISO 5834 -2) Type 1 and can be used in place of the metal backed solution (metallic tibial tray + UHMWPE tibial insert).

The fundamental scientific technology of the modified devices has not changed relative to the predicate devices. The safety and effectiveness of the GMK Full PE Tibial Components are adequately supported by the substantial equivalence information, materials information, and analysis data provided within this Premarket Notification.

Performance Testing

The GMK Full PE Tibial Components was tested for the following compared to the predicate devices:

- Breakage
- Implant detachment
- Excessive wear of the articulating surface
- Femoral luxation or subluxation due to insufficient constraints
- Insufficient mobility and/or Range of Motion (ROM) according to ASTM 2083

A review of the mechanical data indicates that the GMK Full PE Tibial Components is equivalent to devices currently cleared for use and is capable of withstanding expected in vivo loading without failure.

Conclusion:
Based on the above information, the GMK Full PE Tibial Components can be considered as substantially equivalent to its predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

Medacta International SA
% Mr. Adam Gross
Director of Regulatory, Quality and Compliance
Medacta USA
4725 Calle Quetzal, Unit B
Camarillo, California 93012

August 22, 2013

Re: K131310
Trade/Device Name: GMK Full PE Tibial Components
Regulation Number: 21 CFR 888.3560
Regulation Name: Knee joint patellofemorotibial polymer/metal/polymer semi-constrained cemented prosthesis
Regulatory Class: Class II
Product Code: JWH
Dated: July 2, 2013
Received: July 3, 2013

Dear Mr. Gross:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21

CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson -S

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K131310

Device Name: GMK Full PE Tibial Components

Indications for Use:

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Prescription Use ____x___ AND/OR Over-The-Counter Use _____
(21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Casey L. Hanley, Ph.D.

Division of Orthopedic Devices